DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA CERTIFIED MAIL

WARNING LETTER

FLA-04-15

February 4, 2004

Anthony (nmi) Lombardi, Jr., President
Lombardi's Seafood Inc.
7491 Brokerage Drive
Orlando, Florida 32809

Dear Mr. Lombardi,

We inspected your firm at the above address, on October 10, 14, 15 and 17, 2003. This inspection was conducted as part of an investigation of a scombroid poisoning outbreak. During the inspection, we found that you have serious deviations from the Seafood HACCP regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your fishery products are adulterated, in that the histamine-forming fish and ready-to-eat fishery products such as vacuum packaged smoked fish, canned pasteurized crabmeat, and smoked fish dip products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However your firm does not have HACCP plans for your ready-to-eat fishery products, such as vacuum packaged smoked fish and canned pasteurized crabmeat to control the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum*. In addition, your firm does not have a HACCP plan for ready-to-eat seafood salad or dip products received by your firm such as smoked fish dip to control the food safety hazard of pathogen growth and toxin formation.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Raw Fish, including histamine-forming fish, fails to list a critical limit for fish that have been transported in excess of 4 hours to control the hazard of histamine formation. Our investigation determined that some of your histamine species are transported longer than 4 hours.

FDA recommends a method of assuring that these types of products are adequately cooled throughout transportation. When transportation is in excess of 4 hours, we suggest either monitoring the adequacy of the cooling media at receipt or obtaining documentation of continuous temperature monitoring during transport. (These recommended methods may also be applied to seafood transported less than 4 hours.)

3. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP plan for Raw Fish, including histamine-forming fish, lists a monitoring procedure at the Cooler critical control point that is not adequate to control the food safety hazard of histamine formation. Your plan lists that you will monitor cooler temperatures periodically throughout the day. FDA does not consider intermittent temperature checks during storage periods to be an adequate method of assuring that histamine-forming fish are held at safe temperatures throughout storage. If your products are not stored with ice or cooling media, FDA recommends a method of continuous temperature monitoring, such as a time/temperature data logger, recorder thermometer, or a high temperature alarm with 24 hour monitoring, with a visual check of the instrument at least once per day. If all of your histamine-forming fish products are stored completely surrounded with ice or cooling media, FDA recommends monitoring the adequacy of the ice or cooling media twice a day.

4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for Breaded Seafood Products at the Batter critical control point to control pathogen growth and toxin formation, specifically *Staphylococcus aureus*, is not adequate. Exposure times greater than three hours cumulatively at 70° F could result in toxin formation. We suggest that you revise your plan to either specify a maximum temperature value or to specify the maximum time value that batter temperature can exceed 70° F.

5. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or may have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm's all-inclusive, imported fish product specification does not address the specific hazards associated with species or processing activities for the various products you import. Specifically, your product specification does not address the hazards of histamine associated with the Mahi Mahi and Marlin you import from Costa Rica and ciguatera associated with the snapper you import from Costa Rica. The FDA import database shows that you also import pasteurized crabmeat from Mexico. Your product specification should address the *Clostridium botulinum* hazard associated with your imported pasteurized crabmeat.

These serious seafood HACCP deficiencies are of particular concern based on the evidence linking your firm to a recent scombroid poisoning outbreak with raw frozen tuna. The responsible toxin in the tuna, histamine, is a direct result of time and temperature abuse which could have occurred while the tuna was in your possession or prior to your receipt of the tuna. The levels of histamine determined by our laboratory are indicative of substantial abuse which would be readily apparent organoleptically. We recommend that you re-evaluate your seafood HACCP program and import procedures at your facility to ensure their efficacy. Your analysis of your HACCP program may determine that additional corrections or modifications to your program are necessary, in addition to the deviations we have noted in our investigation, to assure that future safety issues with products you market are controlled.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as new or revised HACCP plans, product specifications and completed monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari H. Shambaugh, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Shambaugh at (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District